ORGANIC MATERIALS REVIEW INSTITUTE

Comments on USDA National Organic Program
Proposed Amendments to the
National List of Allowed and Prohibited Substances
7 CFR Part 205, Docket No.TMD-03-02

June 2, 2003

Richard Mathews Program Manager National Organic Program USDA-AMS-TMP-NOP 1400 Independence Ave., SW, Room 4008 So. Ag Stop 0268 Washington, D.C. 20250

RE: Docket No. TMD-03-02

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Dear Mr. Mathews:

OMRI appreciates the opportunity to comment on the proposed amendments to the USDA National List of Allowed and Prohibited Substances (National List), Docket Number TMD-03-02. OMRI supports the National Organic Program (NOP) for making technical corrections that were needed in the National Organic Standards (NOS) and for incorporating recommendations of the National Organic Standards Board (NOSB). OMRI offers additional corrections for further improvements to the National List (§§205.600 through 205.607). Our goal is to bring attention to the intent of the public process as set out in the Organic Foods Production Act of 1990 (OFPA). With respect to this Docket, as we also did in our April 16, 2003 Docket (TMD-02-03) comments, we would like to comment on the advisory function of the NOSB for implementing and amending the National List as well as the need for adequate opportunities for public comment on NOSB recommendations and proposed amendments to the National List.

As also noted in our comments on the April 16, 2003 Docket, NOSB recommendations reflect an extensive evaluation of issues raised in public NOSB meetings, by Technical Advisory Panels (TAP), and through the petition process. The absence of NOSB recommendations from this Docket imposes unnecessary delays on the development of a comprehensive National List, which do not serve the public interest nor the well being of the organic industry. In these comments, OMRI would again like to raise issues associated with the regulatory procedures for proposed amendments and to draw attention to further improvements in the National List that can be implemented by better utilizing the statutory mission of NOSB. We would again like to emphasize that the strength of the NOP is in the public partnership that OFPA established between it and the NOSB. OMRI encourages a continued development of that partnership.

Public Comment Period

We request a minimum comment period of 30 days for all future amendments to the NOS (7 CFR Part 205). In the Preamble of this Docket and the April 16, 2003 Docket, the NOP stated, "...a 10-day period for interested persons to comment on this rule is appropriate." According to a clarification of this policy offered on May 15, 2003 by Barbara Robinson at the *All Things Organic* Conference, the comment period

was reduced to 10 days to speed the process for adding long-awaited amendments to the National List. Ms. Robinson noted that a public comment period had already been met due to the fact that the NOSB recommendations were crafted with public comment taken into account.

OMRI would like to point out discrepancies and issues that have been overlooked by this abbreviated comment-period policy. The NOP has not abided by its claim of a 10-day comment period. For the April 16, 2003 Docket, comments were due on April 28, 2003. During this period, two major religious holidays occurred shortening the actual eight-day period to six days. This current Docket was posted on May 22, 2003 with a major holiday falling during its comment period, setting a six-day period. Presuming that the NOP was not including the two weekends and holidays (Passover, Good Friday, and Memorial Day) occurring during the respective comment periods for these two Dockets, it is difficult to discern the reasoning for its 10-day count. By shortening the comment period to six business days, the NOP has effectively closed the opportunity for comment from interested parties and members of the public who either were unable to comment during the NOSB meetings where the National List recommendations were made or who take issue with an NOSB recommendation and/or its handling by the NOP in adding it on the National List.

Given the careful deliberations that have characterized the National List, a rushed comment period is without precedent and does harm to the integrity of the NOS. OMRI requests a full justification for establishing this abbreviated comment process and a clarification for how the NOP has calculated the so-called 10-day comment period.

NOSB Recommendations Not Included

In the proposed rule notice, the NOP states, "This proposed rule would amend the National List to reflect recommendations submitted to the Secretary by the NOSB from November 15, 2000 through September 17, 2002. Between the specified time period, the NOSB has recommended that the Secretary add five substances to §205.605 of the National List based on petitions received from industry participants." This statement does not accurately report the number of NOSB processing material recommendations that were made in this period. In actuality, the NOSB has recommended addition of three substances to §205.605(a), eight substances to §205.605(b), and two substances to §205.606. It also recommended revisions of two annotations in §205.605(b) for ethylene (degreening of citrus) and potassium hydroxide (peeling of peaches). Table 1 contains a complete list of NOSB recommendations, including those recently made on May 14, 2003, which have not been addressed by either this Docket or the April 16, 2003 Docket.

The NOS and the National List should be updated to reflect NOSB recommendations. Absence of many of the NOSB recommended materials from the National List and the proposed amendment Dockets (April 16, and May 22, 2003) creates undue hardships for the organic industry. If there are cases where the USDA believes it is justified in not accepting the NOSB's recommendations, such cases should be explained and justified in the Federal Register.

In this regard, OMRI requests a a regulatory justification for the absence of the following NOSB-recommended materials from this Docket and the reasoning for their continued status as prohibited materials.

Activated carbon is a widely used filtering aid that is similar in function to powdered cellulose, a material that was added to this Docket. Activated carbon is considered a secondary direct additive when used as a boiler chemical. It is also considered a processing aid that is not listed as a food contact substance for filtering uses under FDA regulations. It is similar in function to other filtering aid materials already included on the National List, e.g., perlite and diatomaceous earth.

Similarly, the NOSB approved limited use of certain volatile **boiler chemicals** (ammonium hydroxide, cyclohexylamine, diethylamino-ethanol, octadecylamine) that are considered secondary direct food additives under FDA regulations. These materials were recommended after a lengthy review and public comment.

Peracetic acid, a sanitizing agent used in rinse and wash water, was recommended by the NOSB in November 2000. It is a valuable tool for managing food safety, having advantages over chlorine (i.e., does not form trihalomethane compounds, is not corrosive to equipment) and is available for use in commercial applications. The continued absence of peracetic acid from the National List deprives the organic industry of a needed "green" post-harvest handling material.

As OMRI has already noted in its comments on the April 16, 2003 Docket, the NOSB recommended **orange shellac** and **gelatin** as permitted additives in May 2002. The continued prohibition of shellac, used as a component in fruit coatings, will mean that these formulations may not be available in time for the 2003 citrus crop.

NOSB voted that shellac and gelatin are deemed to be "agricultural" ingredients subject to the requirements of §205.606 regarding commercial availability. NOP has yet to clarify the term "commercial availability" in the NOS. Given that public comment has already been received during the comment period for the December 21, 2000 Final Rule, NOP's failure to address this issue produces further hardships for the industry and public in dealing with the vagueness of interpreting §205.606. OMRI requests an explicitly stated standard regarding commercial availability, particularly with respect to the framework of §205.606 – i.e., all substances deemed agricultural and subject to requirements for commercial availability should be listed in section §205.606. The criteria for determination of commercial availability should be developed with an opportunity for further public input. We recommend that the approved status of shellac and gelatin, as well as other materials to be covered by this section, be clearly identified in this section of the National List

We are also concerned that the 13 high-priority livestock medications approved by the NOSB have not been included in the proposed amendments, particularly given the urgency with which they were addressed by the NOSB (See OMRI comments on Docket TM-02-03). In October 2002, NOSB also recommended a specific allowance for excipients used in animal drugs to permit formulations of medical products containing approved active ingredients. We hope these missing items will be the subject of a forthcoming proposed amendment Docket, out of concern for prudent farm management and animal welfare.

Suggested Changes

1. Cellulose – The listing of this material should be adjusted to accurately reflect the technical form of the substance. We suggest the following changes (underlined and strikeout):

205.605(b)...(i) cellulose, <u>powdered</u> --for use in regenerative casings, as anti-caking agent (non-chlorine bleached) and filtering aid 205.605(b)...(ii) cellulose, as regenerative casings.

These two distinct forms of cellulose should be listed as separate materials to avoid confusion with other cellulose derivatives that are used as food additives and have been rejected by the NOSB, e.g., Hydroxypropyl methylcellulose (HPMC) and Microcrystalline cellulose (MCC). The term "powdered cellulose" is recognized as a specific, less highly refined food additive and should be explicitly listed by this name. For clarity OMRI suggests that NOP include all the Food

and Agriculture Organization (FAO) Individual Numbering System (INS) numbers to identify food additives, which may go under different names, in all future Dockets.

2. Tetrasodium pyrophosphate (TSPP) -- We find the annotation for "use only in textured analog meat products" to be vague. This expression is not a well-defined food term and the absence of a NOS definition leaves its applicability unclear. We also request clarification of the types of food products for which TSPP is approved. According to the proposed amendment listing, it appears that any non-meat-based product that makes an artificial meat claim may qualify under the NOS.

Due to this vagueness in definition and applicability, we believe the listing of TSPP will be inconsistently implemented by certification agencies. Also, the primary use of TSPP appears to be for creating a texture that is similar to a meat product. However, this use directly conflicts with the criterion established at §205.600(b)(4), which states:

"The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive values lost during processing..."

The NOSB received information regarding the intended use, alternatives, and functionality of TSPP from the petitioner prior to its September 19, 2002 meeting and did not provide this information to the public. As a processing aid that is exempt from labeling in the final product under FDA regulations, the inclusion of TSPP in organic products without clear consumer identification presents additional concerns. The lack of transparent review in the TSPP evaluation undermines both the collaborative NOSB-public review process of materials and the integrity of the NOS.

OMRI recommends an extended review and comment period for TSPP in view of the desirability for international harmonization of organic standards. This six-day comment period is not sufficient for interested international parties to comment.

Also relevant to these points on transparency and adequate public comment period for TSPP is the handling of sodium acid pyrophosphate or SAPP during the May 2003 NOSB meetings. This substance was recommended (May 14, 2003) by the NOSB without public availability of the TAP review documents or petitions. OMRI requests that both NOSB recommendations be tabled until further review when both TSPP and SAPP can be opened to a fair public review. OMRI also requests that all information supporting the TSPP and SAPP decisions be made publicly available for comment prior to any listing in a final amendment to the National List.

With respect to the current amendment to add TSPP to the National List, OMRI believes an additional period of public review and comment is justified for the following reasons:

- (1) concerns raised in the TAP review;
- (2) additional information, which was used in the decision making leading to the recommendation for listing TSPP, was apparently provided to the NOSB outside of a public meeting; and
- (3) questions regarding TSPP's acceptability under both the NOP and internationally recognized criteria.

We request that TSPP be withdrawn from the current Docket pending further clarification and more opportunity for public comment.

- 3. **Potassium hydroxide** As with TSPP, OMRI believes that the organic community should have more than six days to comment. Potassium hydroxide's annotation should be drafted in a way that respects the intent of the NOSB while being fair to the entire organic community.
 - The TAP reviewed broader uses and made recommendations regarding the mitigation of the environmental impacts associated with using this substance. While these may be covered in the handling plan, it is not clear how either the NOSB or the NOP can justify the narrowly drafted annotation proposed in this Docket, which permits use as a peeling agent only for peaches using the IQF process. OMRI believes that all parties who are impacted by these proposed changes should have an opportunity to voice their concerns in a comment period. While OMRI does not oppose this annotation as proposed, the lack of time for comment causes concern about fairness and consistency. Therefore, OMRI recommends that this material should be subject to a longer comment period.
- 4. **Remove Natural Colors** This amendment to the processing section of the National List once again fails to remove Natural Colors from the regulation. This substance was never reviewed by NOSB and cannot be listed without violating OFPA at §6517(d)(2) which states—"*No additions*" unless recommended by the NOSB. OMRI believes that "natural colors" may be primarily synthetic, do not have a FDA or NOSB definition and should not be included. Please explain the justification for their continued inclusion.

Conclusion

We would like to stress the importance of following good administrative procedure in opening the proposed amendment Dockets to public comment for a period that provides adequate time for review and preparation of comments. Transparency is a critical component of the regulatory process set out in OFPA, which envisions a collaborative relationship between the NOSB and NOP to provide the public and industry with standards of high integrity. The public role in participating in this process is equally important. The abbreviated comment period for this Docket, as well as for the April 2003 Docket, places a hardship on the industry and the public. The limited comment period and issues associated with the public's exclusion from the review of certain materials also jeopardize the objectivity and transparency of the NOS.

OMRI appreciates the opportunity to comment on these proposed amendments. We support the work of the NOP and NOSB in developing the National List. We also support a public process that maintains a strong organic program to ensure continued success for organic producers. We would appreciate a response from the NOP on the points raised in these comments and look forward to a more transparent process in the future amendments that will be proposed.

Res	pectfully	z subn	nitted.

Laura Morrison
Executive Director

Table 1. Processing Substances recommended by the NOSB: November 2000 – May 2003

Material	NOSB Recommended Category	NOSB Date of Vote	NOSB Recommendation and Annotation	NOP Docket Language 68 Fed. Reg. 27943, May 22, 2003 (7 CFR 205): additions and changes to December 21, 2000 NOP Rule
Processing				
activated carbon	205.605(b)	9-19-02	Allowed with the annotation: from vegetative sources only for use as filtering aid	Not added.
ammonium hydroxide	205.605(b)	10-16-01	Synthetic, allowed. For use as a boiler additive only until Oct. 21, 2005	Not added.
calcium sulfate	205.605(a)	05-01	Nonsynthetic. <u>Allowed from</u> nonsynthetic sources only.	205.605(a) Calcium sulfate - mined
cellulose	205.605(b)	10-16-01	Synthetic, allowed. For use in regenerative casings, as anticaking agent (non-chlorine bleached) and filtering aid.	205.605(b) cellulosefor use in regenerative casings, as anti-caking agent (non- chlorine bleached) and filtering aid
cyclohexylamine	205.605(b)	10-16-01	Synthetic, allowed. For use only as boiler water additive for packaging sterilization only.	Not added.
diethylamino- ethanol	205.605(b)	05-07-02	Synthetic, allowed. For use only as boiler water additive for packaging sterilization only.	Not added.
enzymes, animal derived	205.605(a)	11-16-00	Nonsynthetic, allowed. Rennet (animal derived); catalase (bovine liver); animal lipase; pancreatin; pepsin; trypsin.	Added as synthetic – 205.605(b)(a) Animal enzymes Rennet animals derived; Catalase -bovine liver; Animal lipase; Pancreatin; Pepsin; Trypsin.
Egg white lysozyme	205.605(a)	05-14-03	Allowed, as an animal derived enzyme	Not added
gelatin	205.606	05-07-02	Approved as agricultural, must be from organic source when commercially available	Not added.
glucono delta- lactone	205.605(a)	09-19-02	Nonsynthetic, Allowed with the annotation: produced through microbial fermentation of carbohydrates only.	205.605(a) Glucono delta- lactone
hydroxypropyl methylcellulose (HPMC)		09-19-02	Prohibited, for use in Made with Organic category and Organic	Not added.
octadecylamine	205.605 (b)	10-16-01	Synthetic, allowed. For use only as boiler water additive for packaging sterilization only.	Not added.
L-malic acid	205.605(a)	05-14-03	Nonsynthetic, allowed, <u>from</u> microbial fermentation of <u>carbohydrate substances</u>	Not added

Material	NOSB Recommended Category	NOSB Date of Vote	NOSB Recommendation and Annotation	NOP Docket Language 68 Fed. Reg. 27943, May 22, 2003 (7 CFR 205): additions and changes to December 21, 2000 NOP Rule
microorganisms	205.605(a)	05-14-03	Nonsynthetic, allowed, any food grade fungi, bacteria, and other microorganisms	Not added
peracetic acid	205.605(b)	11-16-00	Synthetic, allowed. For direct food contact only in wash and/or rinse water. Allowed as sanitizer on surfaces in contact with organic food.	Not added.
potassium hydroxide	205.605(b)(27)	10-16-01	Synthetic, allowed. Amend annotation to read: Prohibited for lye peeling of fruits and vegetables except when used for peeling peaches during the individually quick frozen production process.	205.605(b) Potassium hydroxide - Prohibited for lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQP) (IQF) production process.
sodium acid pyrophosphate	205.605(b)	05-14-03	Allowed, <u>for use only as a leavening agent</u>	Not added
shellac, orange deflaked (unbleached)	205.606	05-07-02	Approved as agricultural, must be organic when available	Not added.
tetrasodium pyrophosphate	205.605(b)	09-19-02	Allowed with the annotation: for use only in textured meat analog products	205.605(b) Tetrasodium pyrophosphate- for use only in textured meat analog products